Attorney's Docket No.: 18554-035001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert A. Rabiner et al. Art Unit: 3737

Serial No.: 10/774,985 Examiner: Nasir Shahrestani

Filed : February 9, 2004 Conf. No. : 9583

Title : APPARATUS AND METHOD FOR AN ULTRASONIC MEDICAL DEVICE

OPERATING IN A TORSIONAL MODE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Pursuant to United States Patent and Trademark Office OG Notices: 12 July 2005 - New Pre-Appeal Brief Conference Pilot Program, a request for a review of identified matters on appeal is hereby submitted with the Notice of Appeal. Review of these identified matters by a panel of examiners is requested because the rejections of record are clearly not proper and are without basis, in view of a clear legal or factual deficiency in the rejections. All rights to address additional matters on appeal in any subsequent appeal brief are hereby reserved.

Claims 4, 13, 16, 28, 31, 33-63, and 71 were previously cancelled. Claims 1-3, 5-12, 14, 15, 17-27, 29, 30, 32, 64-70, and 72-78 are presented for examination.

Claims 1-3, 6, 7, 9-11, 17, 19-22, 25, 26, 32, 64-66, 68, 69, 72, 73, and 76-78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication 2001/0047166 ("Wuchinich") in view of U.S. Patent Application Publication 2003/0045887 ("Sakurai") and further in view of U.S. Patent 5,269,297 ("Weng"). But Wuchinich, Sakurai, and Weng, taken alone and in combination, fail to disclose or render obvious a probe that is configured such that cavitation is produced, in a medium surrounding the probe, along a portion of the probe having a radially asymmetric cross section when the portion of the probe having the radially asymmetric cross section torsionally vibrates during use, as required by Applicants' claims 1-3, 6, 7, 9-11, 17, 19-22, 25, 26, 32, 72, 73, 76, and 77, or a probe configured to produce cavitation, in a medium surrounding the probe, along a portion of the probe having a radially asymmetric cross section when the portion of the probe having the radially asymmetric cross section torsionally vibrates during use, as required by Applicants' claims 64-66, 68, 69, and 78.

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Serial No.: 10/774,985 Filed: February 9, 2004

Page : 2 of 5

With regard to the above-noted language of Applicants' claims, the Examiner argued that "functional language does not overcome the prior art which teaches all the components of the claimed limitations" and that "Applicants (sic) intended use is not sufficient to overcome the prior art." Office action mailed April 3, 2008, p. 2. However, the above-noted language of Applicants' claims is not merely functional language or a statement of intended use. Rather, this language recites that the probe is configured such that cavitation is produced (or configured to produce cavitation) along a portion of the probe having a radially asymmetric cross section when the portion of the probe having the radially asymmetric cross section torsionally vibrates. Thus, this language relates to a structural limitation of the probe. See, e.g., In re Venezia, 530 F.2d 956, 958 (CCPA 1976) (holding that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly). Moreover, even if the above-noted language of Applicants' claims could be considered functional language, it is well established that "[a] patent applicant is free to recite features on an apparatus either structurally or functionally." In re Schreiber, 128 F.3d 1473, 1478 (Fed. Cir. 1997) (citing In re Swineheart, 439 F.2d 210, 212 (CCPA 1971)); see also MPEP § 2173.05(g). It is equally well established that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (quoting In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970)). Thus, an assessment of the patentability of Applicants' claims must take into consideration each of the features, whether structural or functional, of the above-noted language of Applicants' claims.

The cited prior art references do not disclose or render obvious all the features of Applicants' claims. In rejecting claims 1-3, 6, 7, 9-11, 17, 19-22, 25, 26, 32, 64-66, 68, 69, 72, 73, and 76-78, the Examiner noted that Wuchinich fails to disclose "operating at the resonant frequency of the transducer," but contended that it would have been obvious to a person or ordinary skill in the art, in view of Sakurai, to modify Wuchinich's device to include this feature,

Serial No.: 10/774,985 Filed: February 9, 2004

Page : 3 of 5

which, according to the Examiner, is disclosed by Sakurai. Office action mailed April 3, 2008, p. 4. The Examiner also acknowledged that Wuchinich and Sakurai fail to disclose an ultrasonic probe configured to produce cavitation, but contended that it would have been obvious to a person of ordinary skill in the art, in view of Weng, to modify the device resulting from the combination of Wuchinich and Sakurai to include "means for the ultrasonic probe to produce cavitation along the longitudinal axis in a medium surrounding the probe during use in order to destroy a thrombus in the patient's blood vessel." Id.

However, even if Wuchinich, Sakurai, and Weng were combined, the resulting device would not include a probe that is configured such that cavitation is produced (or a probe configured to produce cavitation), in a medium surrounding the probe, along a portion of the probe having a radially asymmetric cross section when the portion of the probe having the radially asymmetric cross section torsionally vibrates during use, as required by Applicants' claims. Wuchinich describes an ultrasonic tissue dissection system that produces both longitudinal and torsional motion at a tissue contacting tip of a resonator for the purpose of tissue dissection. See, e.g., Wuchinich, paragraph 0062. Wuchinich's resonator includes a portion having an inhomogenous cross section that can help to transform longitudinal motion into longitudinal and torsional motion. See, e.g., id., paragraph 0070. There is no indication, however, that the inhomogenous portion of Wuchinich's resonator, or any other portion of Wuchinich's resonator, is configured to produce cavitation when torsionally vibrated during use. Sakurai similarly describes an ultrasonic calculus treatment apparatus that transmits longitudinal and/or torsional vibration to a distal tip of a vibration transmitting member for contact with a calculus. See, e.g., Sakurai, Abstract; paragraphs 0042-0051. Sakurai notes that the calculus is

¹ It appears that the Examiner relied on Sakurai only for its disclosure of a probe that operates at the resonant frequency of a transducer, but that limitation is only recited in Applicants' dependent claims 72 and 73. Nevertheless, Applicants address the proposed combination of Wuchinich, Sakurai, and Weng with regard to claims 1-3, 6, 7, 9-11, 17, 19-22, 25, 26, 32, 64-66, 68, 69, 72, 73, and 76-78. In the event that the Examiner intended to reject all of the abovenoted claims except for claims 72 and 73 in view of the combined teachings of only Wuchinich and Weng (and not Sakurai), Applicants note that the arguments provided are equally applicable to such a rejection.

Serial No.: 10/774,985 Filed: February 9, 2004

Page : 4 of 5

shattered or broken apart when the vibrating tip comes into contact with the calculus. See, e.g., id., paragraph 0046. Sakurai's vibration transmitting member is not described as having a portion with a radially asymmetric cross section, and there is no indication that any portion of Sakurai's vibration transmitting member is configured to produce cavitation when torsionally vibrated during use. The tip of Weng's device is designed to produce cavitation when the tip is vibrated longitudinally. See, e.g., Weng, col. 6, lines 10-14; col. 10, lines 34-54; col. 14, lines 8-23. There is no indication that Weng's tip is configured to produce cavitation when torsionally vibrated. Thus, Wuchinich, Sakurai, and Weng, taken alone and in combination, fail to disclose each and every limitation of Applicants' claims.

In addition, a person of ordinary skill in the art, after reading Weng, would not have modified Wuchinich's device or any device resulting from the combined teachings of Wuchinich and Sakurai to include a probe that is configured such that cavitation is produced (or a probe configured to produce cavitation), in a medium surrounding the probe, along a portion of the probe having a radially asymmetric cross section when the portion of the probe having the radially asymmetric cross section torsionally vibrates during use, as required by Applicants' claims. As discussed above, Weng does not disclose such a probe. Rather, Weng describes an ultrasonic transmission apparatus 10 that includes a tip that is designed to optimize cavitation resulting from <u>longitudinal</u> motion of his device. <u>See, e.g., Weng, col. 10</u>, lines 22-54. Weng makes no mention of cavitation resulting from torsional motion or of any probe configured to achieve such cavitation during use. Thus, even if a person of ordinary skill in the art had looked to Weng for ways to modify Wuchinich's device or any device resulting from the combined teachings of Wuchinich and Sakurai, any resulting modification would certainly not have related to the production of cavitation resulting from torsional vibration of a portion of a probe having a radially asymmetric cross section. Thus, Wuchinich, Sakurai, and Weng, taken alone and in combination, fail to disclose or render obvious each and every limitation of Applicants' claims.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection 1-3, 6, 7, 9-11, 17, 19-22, 25, 26, 32, 64-66, 68, 69, 72, 73, and 76-78.

Serial No.: 10/774,985 Filed: February 9, 2004

Page : 5 of 5

Claims 5 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wuchinich, Sakurai, Weng, and U.S. Patent Application Publication 2002/0029054 ("Rabiner"). Claims 8, 12, 14, 15, 24, 27, 29, 30, 67 and 70 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wuchinich, Sakurai, Weng, and U.S. Patent Application Publication 2003/0212331 ("Fenton"). Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Wuchinich, Sakurai, Weng, and U.S. Pat. 6,433,464 ("Jones"). Claims 74 and 75 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wuchinich, Sakurai, Weng, and U.S. Patent 5,935,142 ("Hood"). However, Rabiner, Fenton, Jones, and Hood fail to cure the deficiencies of Wuchinich, Sakurai, and Weng discussed above. Therefore, Applicants request that these rejections be reconsidered and withdrawn.

Payment for the Notice of Appeal is enclosed. No additional fees are believed to be due in connection with the filing of this request for review. However, to the extent fees are due, or if a refund is forthcoming, please adjust deposit account 06-1050, referencing attorney docket number 18554-035001.

Respectfully submitted,

Date: June 17, 2008

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